

498-67

HIGH STRENGTH AND HIGH DENSITY INTRALUMINAL WIRE STENT

Inventors: James J. Rudnick
Dominik M. Wiktor

09977823-104501

HIGH STRENGTH AND HIGH DENSITY INTRALUMINAL WIRE STENT1 FIELD OF THE INVENTION:

The present invention relates generally to implantable intraluminal stents and more particularly, the present invention relates to an improved high strength intraluminal stent having increased wire density.

BACKGROUND OF THE INVENTION:

It is well known to employ endoprostheses for the treatment of diseases of various body vessels. Intraluminal devices of this type are commonly referred to as stents. These devices are typically intraluminally implanted by use of a catheter into various body organs such as the vascular system, the bile tract and the urogenital tract. Many of the stents are radially compressible and expandable so that they may be easily inserted through the lumen in a collapsed or unexpanded state. Some stent designs are generally flexible so they can be easily maneuvered through the various body vessels for deployment. Once in position, the stent may be deployed by allowing the stent to expand to its uncompressed state or by expanding the stent by use of a catheter balloon.

As stents are normally employed to hold open an otherwise blocked, constricted or occluded lumen; a stent must exhibit a relatively high degree of radial or hoop strength in its expanded state. The need for such high strength stents is especially seen in stents used in the urogenital or bile tracts where disease or growth adjacent the lumen may exert an external compressive force thereon which would tend to close the lumen.

One particular form of stent currently being used is a wire stent. Stents of this type are formed by single or multiple strands of wire which may be formed into a shape such as a mesh coil, helix or the like which is flexible and readily expandable. The spaces between the coiled wire permit such flexibility and expansion. However, in certain

09977823-101501

1 situations, such as when the stent is employed in the
urogenital or bile tract, it is also desirable to inhibit
tissue ingrowth through the stent. Such ingrowth through
the stent could have a tendency to reclose or occlude the
5 open lumen. The open spaces between the wires forming the
stent, while facilitating flexibility and expansion, have a
tendency to allow such undesirable tissue ingrowth.

Attempts have been made to provide a stent which
has less open space and more solid wire. U.S. Patent No.
10 5,133,732 shows a wire stent where the wire forming the
stent is overlapped during formation to provide less open
space. However such overlapping wire increases the diameter
of the stent and has a tendency to reduce flexibility and
make implantation more difficult. It is therefore desirable
15 to provide a wire stent which exhibits high compressive
strength and full flexibility without allowing extensive
ingrowth therethrough.

SUMMARY OF THE INVENTION:

20 It is an object of the present invention to
provide an intraluminal stent which exhibits high
compressive strength and is resistive to tissue ingrowth.

It is a further object of the present invention to
provide a flexible wire stent having high compressive
25 strength and maximum wire density to inhibit tissue
ingrowth.

In the efficient attainment of these and other
objects, the present invention provides an intraluminal
stent including a generally elongate tubular body formed of
30 a wound wire. The wire forming the stent is formed into
successively shaped waves, the waves being helically wound
along the length of the tube. The longitudinal spacing
between the helical windings of the tube is formed to be
less than twice the amplitude of the waves thereby resulting
35 in a dense wire configuration.

0997823-101501

1 As more particularly shown by way of the preferred
embodiment herein, an intraluminal wire stent includes
longitudinally adjacent waves being nested along the length
of the tubular body. The peaks or apices of the
5 longitudinally nested waves are linerally aligned. Further,
the intraluminal stent so constructed would have a
percentage of open surface area in relationship to the total
surface area of the stent which is less than 30% in the
closed state, resulting in less open area upon expansion
10 which would inhibit tissue ingrowth.

BRIEF DESCRIPTION OF THE DRAWINGS:

Figure 1 is a perspective view of a conventional
helical coil formed of a single wound wire.

15 Figure 2 is a perspective view of the stent of the
present invention.

Figure 3 is a perspective view of the stent of
Figure 1 exhibiting longitudinal flexibility.

20 Figure 4 is a schematic showing of one wave of the
wire forming the stent of Figure 2.

Figure 5 is a schematic showing of nested
longitudinally adjacent waves of the stent of Figure 2.

Figure 6 is a perspective view of the stent of
Figure 2 shown in the open or exposed condition.

25 Figure 7 shows a portion of a further embodiment
of a wire used to form a stent in accordance with the
present invention.

30 Figure 8 shows a still further embodiment of a
wire used to form a stent of the present invention,
partially wound around a forming mandrel.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS:

35 A simple helically formed coil spring 10 is shown
in Figure 1. Coil spring 10 is formed of a single metallic
wire 12 which for stent purposes may be formed of a suitably
flexible biocompatible metal. The wire coil spring 10
defines generally a cylindrical tubular shape which is

00977823.101501

1 radially expandable upon application of outward radial
pressure from the interior thereof.

5 The present invention shown in Figure 2, improves
upon the simple coil spring 10 shown in Figure 1. However
with reference to Figure 1, certain terminology used
hereinthroughout may be defined. As mentioned, the spring
defines a generally elongate cylindrically tubular shape
lying along a central axis χ . Wire 12 is helically wound,
for example against a constant diameter mandrel (not shown),
10 to form a longitudinally extending structure consisting of
wire 12 and spaces or pitch 16 therebetween. Each
individual winding 14 may be defined as the wire segment
traversing one complete revolution around axis χ . As the
wire is helically coiled about axis χ , each winding is
15 successively longitudinally spaced from the next adjacent
winding by a given distance.

For present purposes, the axial spacing between
any point on the wire coil spring 10 to the point defining
the next successive winding may be thought of as the pitch
20 16 of the wire coil spring 10. As so defined, the pitch of
the coil spring 10 defines the spacing between windings and
therefore the degree of compactness or compression of the
wire coil spring 10.

Also with reference to Figure 1, as the wire coil
25 spring 10 has a generally cylindrical tubular shape, it
defines an outside diameter d_1 and an inside diameter d_2 ,
which would typically differ by twice the diameter d_3 of wire
12. Further, wire coil spring 10 generally defines an outer
cylindrical surface area along its length which may be
30 thought of as being composed of solid surface portions
defined by the outward facing surface of wire 12 itself and
open surface portions defined by the spaces or pitch 16
multiplied by the number of wire windings 14. The ratio of
open surface space to solid surface space may be varied by
35 varying the so-defined pitch 16 of the wire coil spring 10.
A smaller pitch coil, where the windings are more compacted
or compressed, would result in an outer surface area having

09977823 .101501

1 less open space than a coil formed to have greater spacing
or pitch between the wire windings.

Having set forth the definitional convention used
hereinthroughout, the present invention may be described
5 with reference specifically to Figures 2-6. A wire stent 20
of the present invention is shown in Figure 2. Wire stent
20 is generally in the form of an elongate cylindrically
shaped tubular member defining a central open passage 21
therethrough. Stent 20 is formed of multiple windings 24 of
10 a single wire 22 which in the present invention is metallic,
preferably tantalum, as such wire exhibits sufficient spring
elasticity for purposes which will be described in further
detail hereinbelow.

While stent 20 may be formed by helically winding
15 wire 22 much in a manner shown with respect to Figure 1 to
form wire coil spring 10, the present invention contemplates
preshaping the wire 22 itself along its length prior to
helically coiling the wire.

Referring now to Figure 4, wire 22 in an elongate
20 pre-helically coiled configuration may be shaped in a manner
having a longitudinally extending wave-like pattern. Wave
pattern 25 is defined by a plurality of continuously
repeating wave lengths 27 therealong. It has been found
advantageously that the waves may take the form specifically
25 shown in Figure 4 and 5 for optimum results as a wire stent.
However, for explanation purposes, the wave-like pattern 25
generally functions mathematically as sinusoidal wave,
having a given amplitude A as measured from a central axis
y and a peak-to-peak amplitude of 2A. The wave pattern 25
30 has a uniform preselected period λ equal to the transverse
extent of a single wave length. The geometry of each wave
length 27 is shown in Figure 4.

The wave-like configuration imparted to wire 22
may be accomplished in a variety of forming techniques. One
35 such technique is to pass wire 22 between the teeth of
intermeshed gears (not shown) which would place a generally
uniform sinusoidal wave-like crimp along the length of the

09977823-101501

1 wire. Other techniques may be used to form the specific
 shape shown in Figure 4. Wire 22 may be passed through a
 pair of gear-like overlapping wheels (not shown) having
 depending interdigitating pins. By arranging the size,
 5 position and spacing of the pins, various wave-like
 configurations may be achieved. The particular shape shown
 with reference to Figures 4 and 5 has been selected as each
 wave length 27 includes a pair of non-curved linear sections
 29 between curved peaks 31. As will be described with
 10 respect to Figure 5, this configuration allows the waves to
 be stacked or nested with maximum compactness when the wire
 is helically wound around a forming mandrel (Figure 8) into
 the shape shown in Figure 2.

Referring now to Figure 5, schematically shown is
 15 a portion of stent 20 of Figure 2 which has been cut once,
 parallel to the x axis and flattened after being wound in a
 helical fashion such as that described with respect to the
 wire coil spring 10 of Figure 1. Wire 22 formed in the
 manner shown and described with respect to Figure 4, may be
 20 helically wound around an appropriately shaped mandrel
 (Figure 8). The width of the mandrel is selected in
 combination with the frequency and period of the waves
 forming wire 22 so that upon helical coiling therearound the
 waves forming each winding 24 are longitudinally stacked or
 25 nested within the waves formed by the longitudinally
 adjacent winding successively spaced therefrom.

As can be seen with respect to Figure 5, the peaks
 31 of the waves of longitudinally adjacent windings 24 are
 each linearly aligned so that each wave is stacked or nested
 30 within the next adjacent wave. In optimum configuration,
 the spacing or pitch 26 between each longitudinally
 successive winding 24 is constructed to be minimal.
 However, nesting or stacking does occur where the pitch or
 spacing between longitudinally adjacent windings 24 is less
 35 than $2A$ i.e. the peak-to-peak amplitude. As long as the
 pitch remains less than $2A$ each longitudinally adjacent
 winding 24 will be nested within the wave formed by the

0997823-101501
 TOSTOT-EEB/660

1 previously formed winding 24. By minimizing the pitch or
spacing 26 between adjacent windings 24, the open space
between windings may be minimized. The particular wave-like
5 pattern imparted to wire 22 as shown in Figure 4 allows
particularly tight stacking of longitudinally adjacent
windings.

The particular configuration of the stent 20 shown
in Figure 2, provides significant advantages in medical
applications. The stent 20 of the present invention is
10 typically implanted by means of a balloon catheter (not
shown). The stent 20 in a closed form is held around a
deflatable catheter balloon. The stent is then inserted
into the lumen and located at the desired position. The
shape of the closed stent shown in Figure 2 permits ease of
15 insertability. As shown in Figure 3, the stent may be
easily bent or flexed along its longitudinal extent. The
spacing or pitch 26 of windings 24 facilitate such bending.
This helps in the insertion and deployment of the stent
through a lumen, as typically body lumens traverse a
20 torturous path through the body which must be followed by
the stent which is being deployed therein. Once properly
located, the balloon is inflated and the stent is radially
expanded for deployment. The balloon is then deflated, and
the catheter is removed leaving the expanded stent in place.

25 The windings of stent 20 in closed condition are
tightly nested. The cylindrical surface area formed by the
coiled wire has greater wire density, i.e. more of the
surface area is composed of solid wire while less of the
surface area is composed by open space between the wire
30 windings than in previous non-nested single wire stents.
The wire surface area in the closed condition equals the
wire surface area in an expanded condition. By maximizing
the closed condition wire surface area, even when the stent
is expanded such as shown in Figure 6, the expanded wire
35 surface area is also maximized reducing tissue ingrowth
between the expanded windings of the stent. Contrary to a
simple coil spring such as that shown in Figure 1, the stent

09977823-101501

20 of the present invention expands without significant foreshortening of the stent or rotation of the ends of the coil. Rather, expansion is achieved by a flattening or elongation of the individual waves of the stent 20. Once the stent is expanded after deployment to a shape shown in Figure 6, the increased wire surface area as well as the particular shape of the wire provides sufficient radial strength to resist the compressive forces of a blocked, constricted or impinged upon lumen.

Additionally, the above-described benefits of the stent of the present invention are achieved without the necessity of longitudinally overlapping adjacent wire windings. In many prior art stents, the stents include portions of wire windings which are longitudinally overlapped. This increases the wall thickness of the stent thereat and results in a stent which is more difficult to implant in the body lumen by means of a balloon catheter. Also, such stents create an undesirable, more turbulent fluid flow therethrough. The stent of the present invention maximizes wire density, maintains a high degree of flexibility and radial compressive strength without increasing the stent wall thickness beyond the single wire diameter.

EXAMPLE:

Mathematically, the geometric analysis of the preferred embodiment of the stent of the present invention may be described as follows with reference to Figures 4 and 5.

Each wave length 27 of the wave pattern 25 forming stent 20 is formed to include a straight leg segment 29 with a bend radius at peak 31. The angle at which the helix coils around the center line χ (Figure 1) is assumed to be close to 90° , so that the successive windings 24 are positioned to be as close to concentric as possible while still maintaining a helical pattern.

The integer number of waves N per single circumference or single winding follows the equation:

$$N = \frac{\pi D}{\lambda} ;$$

where D is the diameter of the closed stent and λ is the period of a single wave.

The number of helical windings M per stent is defined by the equation:

$$M = \frac{L \sin \theta}{d_3} ;$$

where L is the overall stent length; θ is the angle of the straight leg segments with respect the line of amplitude of the wave pattern; and d_3 is the wire diameter.

The exterior exposed surface area of the stent is equivalent to the amount of wire packed within a fixed stent length. The total length L_w of wire employed to form the stent follows the equation:

$$L_w = MN \left(4 \ell + 4 \left(r + \frac{d_3}{2} \right) \frac{\pi}{180} (90 - \theta) \right)$$

where r is the radius defining the peak curvative; and ℓ is the length of the straight line segment of the wire.

It follows that the projected solid wire area is $L_w d_3$, and the percentage of open space coverage (% open) is given by the equation:

$$\% \text{ OPEN} = 100 \left(1 - \frac{L_w d_3}{\pi D L} \right)$$

In a specific example, a stent having the parameters listed in Table I and formed in accordance with the present invention yields a percentage of open space (% open) equivalent to 28.959%.

TABLE I

L	Length of Stent	1.000 in
D	Diameter of Closed Stent	0.157 in
d _w	Wire Diameter	0.010 in
r	Radius of Curvature of Peak	0.020 in
N	Number of Waves per Winding	3
M	Number of Windings per Stent	22.47
ℓ	Length of Straight Portion of Stent	0.097 in

Further, it is found that an expanded stent constructed in accordance with the example set forth above, exhibits superior resistance to pressure P acting upon the stent in a radially compressive manner (Figure 6). In the present and illustrative example, P has been determined, both mathematically and empirically, to be 10 psi.

It is further contemplated that the stent of the present invention may be modified in various known manners to provide for increased strength and support. For example the end of wire 22 may be looped around an adjacent wave or extended to run along the length of the stent. The wire may be welded to each winding to add structural support such as is shown in U.S. Patent No. 5,133,732. Also, each windings may be directly welded to the adjacent winding to form a support spine such as shown in U.S. Patent No. 5,019,090.

Further, as mentioned above, wire 22 is helically wound around a mandrel to form the helical pattern shown in Figure 1. While the angle at which the helix coils around the mandrel is quite small, a certain angle must be imparted to the uniform windings to form a coil. It is further contemplated that a helix-like winding may be formed by concentrically wrapping a wave pattern around the mandrel

1 where the length of the sides of each wave are unequal. As
shown in Figure 7 a wave pattern 125 may be formed having
leg segments 129 of uneven length. Wave pattern 125
includes individual wave lengths 127 having a first leg
5 segment 129a and a second leg segment 129b. Leg segment
129a is constructed to be shorter than leg segment 129b.
Thus wave pattern 125 has a step-type shape so that upon
winding around a mandrel, the windings 124 coil in a
helical-like fashion therearound. This provides a
10 lengthwise extent to the coil without having to impart a
helical wrap thereto. Forming the stent length in this
manner may tend to result in better flow characteristics
through the stent in use.

Other modifications which are within the
15 contemplation of the present invention may be further
described. Figure 8 shows a wire 222 which has been
preformed to have a wave pattern 225 which is generally
triangular in shape. This wave pattern 225 includes
individual wave lengths 227 having straight leg segments
20 229a and 229b which meet at an apex 231. Wire 222 so
formed, may be wound around a mandrel 200. As the
individual wave lengths 227 nest in a manner above
described, the apices 231 of the wave length 227 are
longitudinally aligned.

25 The winding of wire 222 around mandrel 200 takes
place in the following manner. The formed wire 222 is held
in position while the mandrel is rotated in the direction of
arrow A, thereby coiling the wire 222 around mandrel 200.
The spacing or pitch 216 is created by subsequent vertical
30 movement of the of the formed wire 222 along mandrel 200
while rotation thereof is taking place. When the winding is
complete, the ends 233 of the wire 222 may be "tied off" by
looping the end 233 around the next longitudinally adjacent
winding.

35 While in the embodiment shown above, the amplitude
of each wave is relatively uniform, it is contemplated that
the wire could be formed to have waves of varied amplitude.

09977823 101501

1 For example, the wire could be formed so that at the ends of
the wound stent the amplitude of the waves is relatively
small while in the central portion of the stent the
amplitude is relatively large. This provides a stent with
5 a more flexible central section and more crush-resistant
ends.

In certain situations the stent of the present
invention may include a membrane covering (not shown) which
would cover the entire stent. The wire surface of the stent
10 would serve as a support surface for the membrane covering.
The membrane covering would act as a further barrier to
tissue ingrowth. Any membrane covering may be employed with
the present invention such as a fabric or elastic film.
Further, this membrane covering may be completely solid or
15 may be porous. In addition, as above described, employing
a formed wire having varied amplitude where the amplitude of
the wire is smaller at the ends of the stent would help
support the membrane covering as the crush-resistant ends
would serve as anchors to support the membrane covering with
20 little support necessary at the more flexible central
section of the stent.

Various changes to the foregoing described and
shown structures would not be evident to those skilled in
the art. Accordingly, the particularly disclosed scope of
25 the invention is set forth in the following claims.

30

35

09977823-101501